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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,085

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Bernard Verrier

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EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1614

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,085	<b>Applicant(s)</b> VERRIER ET AL.	
	<b>Examiner</b> TIMOTHY P. THOMAS	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/2008 has been entered.

### ***Response to Amendment***

2. The declaration under 37 CFR 1.132 filed 9/19/2008 is sufficient to overcome the rejection of claims 2, 4-6 and 8-9 based upon Marcet et al. (British Journal of Pharmacology; 2004; 141, 905-914).

### ***Response to Arguments***

3. Applicants' arguments, filed 9/19/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Applicant's arguments, see p. 2 in view of the claim amendment, filed 9/19/2008, with respect to the rejection(s) of claim(s) 2, 4-9 under 35 USC 112, 1<sup>st</sup> paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows.

***Claim Objections***

5. Claim 8 is objected to because of the following informalities: the two sets of concentrations recited in line 2 of claim 8 are redundant if construed to both represent concentrations of alcohol in some formulation. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites two different amounts recited as concentration ranges, "between 10 and 1000 ppm (parts per million), namely from 10 mg/kg to 1 g/kg". It is not clear whether these amounts are redundant concentration ranges in some composition, recited using two different units, or whether the first range refers to a concentration in a liquid solution (or solid composition) and the second refers to a dosage, since mg/kg are units commonly used in the art to describe an amount dosed to a patient in terms of a drug amount (in mg) per body weight (in kg).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1614

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2, 4-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shefter et al. (US 2002/0032166 A1; 2002 Mar).

Shefter teaches a method of preparing a true homogenous solution of a pharmaceutical substance dissolved in an organic solvent in which the pharmaceutical substance is not normally soluble, by forming a hydrophobic ion

Art Unit: 1614

pair complex involving the pharmaceutical substance and an amphiphilic material (abstract); pharmaceutical substances may be introduced into a human or animal host for therapeutic purposes, which include slow injection of small particles in a liquid and inhalation of small particles in pulmonary delivery, with entry into the circulatory system or release for local treatment in the lungs (paragraph 0003); nebulization and inhalation (paragraph 0005); aerosol and nebulization techniques (paragraph 0105); an ion pair is formed between the pharmaceutical substance and an amphiphilic material, such as a surfactant forming a hydrophobic ion pair (HIP) complex (paragraph 0067); HIP complex may be dissolved in an organic solvent to form a true homogeneous solution, the native tertiary structure of proteins is retained even when dissolved in 1-octanol as the solvent (paragraph 0068); particles in the 2-10 micron range, useful for pulmonary delivery, suitable for DNase, an enzyme currently being used by cystic fibrosis patients to dissolve viscous fluid build-up in the lung (implies administration of DNase to patients with cystic fibrosis; paragraph 0070); solutions having the HIP complex dissolved in the organic solvent are a valuable product (paragraph 0086); subcutaneous injections of organic solutions (paragraph 0192). Shefter does not specifically teach the required administration step of 1-octanol to a patient with cystic fibrosis. It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the DNase (of paragraph 0070) in the form of a true homogeneous solution using 1-octanol as a solvent (such as taught in paragraph 0068) and to administer this DNase solution to a patient with cystic fibrosis pathology, using pulmonary delivery via

Art Unit: 1614

nasal or mouth, or via oral (in a form suitable for buccal administration), or in the form of an aerosol or a nebulized material. The motivation would have been to substitute the particle formulation taught in paragraph 0070 with the homogeneous solution taught in paragraph 0068 with 1-octanol and the DNase, the substitution of one recognized suitable formulation for another. The presence of the surfactant would be considered to satisfy the carrier requirement of claim 7. It is noted that the interaction of 1-octanol with a CFTR in epithelial resulting in opening of the channel is not recognized by Shefter; however, this effect would be expected to accompany administration of the 1-octanol solutions to a patient with cystic fibrosis, suggested by Shefter. It is also noted that a solution of DNase in 1-octanol, (considering dissolution of a HIP complex in 1-octanol as taught in Example 15, esp. paragraph 0187) would contain an amount of 1-octanol greater than the concentration ranges recited in claim 8; and when administered to a patient with cystic fibrosis, would inherently result in an amount of 1-octanol sufficient to generate in the vicinity of CFTR epithelial cell membrane a concentration sufficient to partially or fully open the CFTR in the membrane, required by claim 9.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in

Art Unit: 1614

the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

***Conclusion***

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1614

/Timothy P Thomas/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614